NOV 14 2011

510(k) K102413: Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the FUZE®: Intramedullary Arthrodesis Nail System.

Sponsor:	Vilex in Tennessee, Inc., 111 Moffitt St., McMinnville, TN 37110, 931-474-7550
Contact:	Sylvia Southard Date: Nov 8, 2011
Device Name:	FUZE®: Intramedullary Internal Fixation Nail
Classification:	21 CFR 888.3020 – "Intramedullary Nail" 21 CFR 888.3030 Single/Multiple component metallic bone fixation appliances and accessories; Product Code HSB, Class II
Predicate Devices:	K090857 Ankle Fusion Nail (VALOR™) K021786 Titanium Ankle Arthrodesis Nail (Phoenix) K043052 TriGen Hindfoot Fusion Nail K051590 T2 Ankle Arthrodesis Nail K091788 Panta Arthrodesis Nail
Description of Device:	The Vilex FUZE™ is a single-piece intramedullary nail fixed to the tibia and foot with locking cross screws for fusing the ankle joint(s). The FUZE™ is a straight cannulated metallic implant offered in five diameters and various lengths in either 316L VM (ASTM 138) stainless steel or Ti6Al4V titanium alloy (ASTM 136). The FUZE™ System is a modular system consisting of the implant, locking screws, and instrumentation for fixation. The screws, (offered in one diameter and various lengths), are manufactured from identical materials (either stainless steel or titanium alloy, matching the implant). The targeting device is radio translucent, designed to lock into the FUZE™ for the correct insertion of the locking screws. The system also includes drills, reamers, screwdrivers, guide wires and Steinman pins.
Substantial Equivalence	Engineering analysis, cadaver, sawbones, and components tests confirm that the design possesses the mechanical integrity necessary for this application and implant can compress the tibi-talo-calcaneal joints. The design features of the FUZE™ Intramedullary Arthrodesis Nail System are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are indications for use, material of construction, sizes, hole locations, and shape. The safety and effectiveness of the FUZE™ is adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification.
Material:	Titanium Ti6Al4V, ASTM 136 or stainless steel alloy 316L ASTM 138, suitable for human implanting
Indications for Use:	Ankle Arthrodesis, Tibio-talo-calcaneal Arthrodesis
Establishment Reg. No.:	1051526

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Vilex, Inc.
% Ms. Sylvia Southard
111 Moffitt Street
McMinnville, Tennessee 37110

NOV 14 2011

Re: K102413
Trade/Device Name: FUZE Intramedullary Internal Fixation Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: November 8, 2011
Received: November 9, 2011

Dear Ms. Southard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102413

Device Name: FUZE: INTRAMEDULLARY INTERNAL FIXATION NAIL

Indications For Use:

The Vilex FUZE has the following Indications for Use

Ankle Arthordesis, Tibio-talo-calacaneal Arthrodesis

Prescription Use X__
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102413